IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8214

Bartle, C.J. July 1, 2009

The Estate of Helen L. Noble (the "Estate" or "claimant"), a representative claimant under the Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Richard Noble, the spouse of Helen L. Noble and the representative of Ms. Noble's Estate, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Helen L. Noble ("decedent") died on February 23, 2000, at age sixty-one. Richard Noble submitted a completed Green Form to the Trust on behalf of the Estate that was signed by the decedent's attesting physician, Dr. Manoj Muttreja.[4] Based on an echocardiogram dated August 28, 1999, Dr. Muttreja attested in

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3(...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. The Green Form does not reflect when it was received by the Trust. Mr. Noble signed the Green Form in February 2006.

Part II of claimant's Green Form that the decedent suffered from severe mitral regurgitation, an abnormal left ventricular end-systolic dimension greater than 50 mm by M-Mode or 2-D echocardiography, or an abnormal left ventricular end-diastolic dimension greater than 70 mm as measured by M-Mode or 2-D echocardiography, an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension greater than or equal to 45 mm by M-Mode or 2-D echocardiography, and an ejection fraction less than 30%. Dr. Muttreja also attested that the decedent had ventricular fibrillation or sustained ventricular tachycardia, which resulted in hemodynamic compromise. Based on such findings, the Estate would be entitled to Matrix A-1, Level V benefits in the amount of $1,087,718.[5]

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5. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she "otherwise qualifies for payment at Matrix Level II, III or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise." See Settlement Agreement § IV.B.2.c.(5)(d). The Trust does not dispute that the Estate's Green Form, as well as the audit results, support a claim for Level II Matrix Benefits for damage to decedent's mitral valve. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b).

We need not address, however, whether the Estate is entitled to Level II Matrix Benefits for damage to decedent's mitral valve, as the Trust asserts, and claimant does not contest, that the Estate is not entitled to Matrix Level II benefits under the Settlement Agreement because claimant did not opt-out of the Seventh Amendment to the Settlement Agreement, which was

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In November 2006, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists.[6] In audit, Dr. Oliner determined that there was no reasonable medical basis for Dr. Muttreja's finding that the decedent had ventricular fibrillation or sustained ventricular tachycardia, which resulted in hemodynamic compromise, stating that:

> Although the patient had documented nonsustained V.T. during an 8/28/99 to 9/1/99 hospital admission, there is no documented V.F. or sustained V.T. with hemodynamic compromise. Although the death certificate says death was due to cardiac arrest due to "ventricular arrythmias," the records indicate that the patient was found apneic and pulseless with "sporadic agonal activity" on monitor. She was given medicine, CPR and electrical shocks "without response." There was no documented V.F. or sustained V.T. An agonal rhythm is unlikely to have been preceded by VT or VF. Rather, it is much more likely that a bradyarrhythmia lead [sic] to the "cardiac arrest" and death.[7]

5(...continued)
previously approved by this Court. Accordingly, the only issue is whether the Estate is entitled to Level V Matrix Benefits.

6. Pursuant to Pretrial Order ("PTO") No. 3882, all Level III, Level IV and Level V Matrix claims are subject to the Parallel Processing Procedures ("PPP") for Matrix claims asserting high-level medical conditions. As Wyeth did not agree that the Estate had a Matrix A-1, Level III, IV or V claim, pursuant to the PPP, the Estate's claim was audited by the Trust.

7. Dr. Oliner also concluded that decedent had mild aortic regurgitation and, as such, there was no reasonable medical basis for Dr. Muttreja's finding of no aortic regurgitation. Dr. Oliner also determined that there was a reasonable medical basis
(continued...)

Based on the auditing cardiologist's diagnosis, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.[8]

In contest, the Estate argued that its claim for Level V benefits should be paid because:

> The Attesting Cardiologist's finding of ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic compromise is supported by the enclosed Declaration of Dr. Manoj R. Muttreja, the Certificate of Death,[9] the history of the [decedent] and the assessments of her conditions that are set forth in her medical records, and the medical literature that is attached to the Declaration of Dr. Manoj R. Muttreja.[10]

7(...continued)
for Dr. Muttreja's finding that the decedent had an abnormal left ventricular dimension. These findings are not at issue.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the present claim.

9. Decedent's death certificate lists the cause of death as cardiac arrest as a consequence of ventricular arrythmias and congestive heart failure.

10. According to the Estate, the medical articles that were attached to the Declaration of Dr. Muttreja establish that:

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In his Declaration, Dr. Muttreja, stated in relevant part, the following:

> Among other things, I reviewed a copy of the above-referenced patient's echocardiogram dated 8/28/99, the hospital records and other medical records concerning the patient, the reports concerning echocardiograms that were performed on 8/28/99 and 2/17/00, the cardiac catheterization report dated 8/30/99, the Emergency Medical Services (EMS) report dated 2/23/00, the Certificate of Death, and the report of the Auditing Cardiologist.
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> Contrary to the Auditing Cardiologist's statement, the presence of an agonal rhythm does not even suggest that a bradyarrhythmia preceded the agonal rhythm. An agonal rhythm is an end-stage arrhythmia. It may be preceded by either a bradyarrhythmia or a tachyarrhythmia, such as ventricular fibrillation or sustained ventricular tachycardia with hemodynamic compromise.
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> According to the Certificate of Death that was signed by J.T. Johnston, M.D., ventricular arrhythmias preceded the

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10(...continued)

> [S]tudies have been performed on numerous patients who had Ejection Fractions of 35% or less, NYHA Functional Class II or III symptoms, PVCs, and nonsustained ventricular tachycardia. According to these articles, sudden cardiac death or death due to tachyarrhythmias was the major cause of death in these patients. The [decedent] had a history that was identical to the history of the patients used in these studies. Therefore, it is reasonably certain that her death was caused by ventricular fibrillation or ventricular tachycardia which resulted in hemodynamic compromise up to the point of her demise.

patient's cardiac arrest. Apparently, Dr. Johnston was familiar with the patient's history of cardiomyopathy and Congestive Heart Failure, and he was aware of the mechanism whereby these conditions lead to ventricular arrhythmias followed by cardiac arrest. Apparently, the Auditing Cardiologist was somehow unfamiliar with this mechanism.

In the History and Physical dated 8/28/99, the Attending Cardiologist, Dr. John E. Lasseter, noted that the patient had a current history that included some lightheadedness, dizziness, near-syncope, palpitations, and occasional heart racing. During the patient's hospitalization from 8/28/99 to 9/1/99, the patient had several episodes of nonsustained ventricular tachycardia or sustained ventricular tachycardia with as many as sixteen (16) beats. The electrophysiologic test was performed by the attending physicians in order to attempt to induce tachyarrhythmias. There was never any prior or present history of bradyarrhythmias or a diagnosis of bradyarrhythmias. Therefore, on the basis of the patient's history and her diagnosis, the most likely cause of her death was a cardiac arrest that was preceded by ventricular tachyarrhythmias.

According to the attached medical literature, sudden death from cardiac causes is a major or leading cause of death in patients with heart failure, and patients with nonischemic dilated cardiomyopathy are at a substantial risk for sudden death from cardiac causes. In the medical literature, "sudden death from cardiac causes" means death that is immediately preceded by ventricular tachyarrhythmias.

Based upon my review of the echocardiogram dated 8/28/99 and the medical evidence that is set forth in paragraph 1, this patient suffered from heart failure, or more specifically, she suffered from nonischemic

> dilated cardiomyopathy. On the echocardiogram dated 8/28/99, I found an ejection fraction less than 30% and an abnormal left ventricular end-systolic dimension (see Part II of the Green Form). The medical records confirm that this patient had severely reduced left ventricular function and a dilated left ventricle that was not secondary to ischemia. In this condition, the patient was prone to experience ventricular tachyarrhythmias.
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> Based upon my review of the material that is set forth in paragraph 1, it is my opinion that the above-referenced patient had ventricular fibrillation and/or sustained ventricular tachycardia which resulted in hemodynamic compromise followed by the death of this patient.

Based on the Estate's contest, the Trust submitted the claim to Dr. Oliner for a second review. Dr. Oliner confirmed his previous conclusion that there was no reasonable medical basis for the attesting physician's finding of ventricular fibrillation or sustained ventricular tachycardia, which results in hemodynamic compromise. Specifically, Dr. Oliner stated, in relevant part, that:

> In accordance with the Trust's request, I again reviewed the entirety of [decedent's] August 28, 1999 echocardiogram tape, as well as Claimant's Contest Materials.
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> Based on my review, I again confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding of ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.
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> In addition, I find that Claimant's Contest Materials fail to establish a reasonable

medical basis for the Attesting Physician's finding of ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

During my initial review of this Claim at audit, I stated that while the death certificate states that [decedent's] death was due to "ventricular arrhythmias," the documentation of an agonal rhythm prior to death suggests that a bradyarrhythmia, rather than ventricular tachycardia or ventricular fibrillation, lead [sic] to [decedent's] cardiac arrest and death. After review of the materials submitted at Contest, I confirm my finding.

Medical records suggest that [decedent] experienced sudden death. Most patients who die in this manner experience ventricular tachycardia or ventricular fibrillation. However, patients who experience ventricular fibrillation (either preceded by ventricular tachycardia or as a primary event) typically do not then develop an agonal rhythm. Thus, it is much more likely that a bradyarrhythmia caused [decedent's] sudden death.

Accordingly, [decedent's] medical records suggest that [decedent] is in a minority of patients where sudden death is *not preceded by ventricular fibrillation or tachycardia*. Rather, [decedent's] medical records suggest that she collapsed and was found in an agonal rhythm, which is bradyarrhythmia. While the death certificate lists "ventricular arrhythmias" as an underlying cause of death, *there is no documentation of ventricular fibrillation or ventricular tachycardia resulting in hemodynamic compromise preceding Claimant's death*. [Emphasis in original.]

While Claimant's expert states at Contest that [decedent] had no history of bradyarrhythmia or of a diagnosis of bradyarrhythmia, this does not establish cause of death. An agonal rhythm is a bradyarrhythmia.

> Accordingly, I confirm my finding that there is no reasonable medical basis for the Attesting Physician's finding of ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

The Trust then issued a final post-audit determination again denying the Estate's claim for Matrix A-1, Level V benefits.[11] The Estate disputed this final determination and requested that the claim proceed to the Show Cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On July 13, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7313 (July 13, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the

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11. In its final post-audit determination, the Trust also noted that it had concluded that the Estate had not established that the decedent ingested diet drugs for a period greater than sixty days. The Estate appealed the Trust's final post-audit determination as to the issue of diet drug usage to arbitration as required by the Settlement Agreement. See Settlement Agreement § IV.C.4.h.-i. See also Audit Rule 18(e). Pursuant to Arbitration Chair Decision No. 16, the Chair of the Arbitration Panel, Gregory P. Miller, directed the Trust to consider the Estate's new evidence as to diet drug usage and determine whether to issue an amended final determination. By letter dated November 16, 2007, the Trust issued an amended determination in which the Trust agreed that the Estate had established diet drug usage greater than 61 days.

Special Master. The Trust submitted a reply on October 19, 2007. The Estate submitted a sur-reply on December 12, 2007.

Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[12] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden in proving that there is a reasonable medical basis for the attesting physician's finding that decedent suffered from ventricular fibrillation or sustained ventricular tachycardia, which resulted in hemodynamic compromise. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Estate's Green Form that is at issue, we must affirm the Trust's

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12. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposition positions" is proper. Id.

final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate asserts that "[t]he opinions of the Treating Cardiologist and Dr. Muttreja, the complete medical history of the [decedent], the medical literature concerning the underlying causes of ventricular tachyarrhythmias, and the treatment protocol that was followed in this case are the reasonable basis that supports the Claimant's claim."[13] The Estate also submitted a Supplemental Declaration of Dr. Muttreja[14], which stated, in relevant part that:

> I reviewed the Declaration of Craig Oliner, M.D., dated 4/24/07. Dr. Oliner erred in his finding that "[decedent] is in a minority of patients where sudden death is not preceded by ventricular fibrillation or tachycardia." Multiple shocks were given by Emergency Medical Services (EMS) personnel. This is the Advanced Cardiac Life Support (ACLS)

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13. The Estate also asserts that the issue of reasonable medical basis should be controlled by the Opinion of Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962). We repeatedly have rejected the Gallagher decision as controlling or persuasive. See, e.g., PTO No. 6275 (May 19, 2006). Nevertheless, for the reasons discussed above, we find that the Estate has established a reasonable medical basis for her claim.

14. The Special Master permitted the Estate to submit the Supplemental Declaration of Dr. Muttreja.

> protocol for ventricular tachycardia/fibrillation and not for bradyarrhythmias. It is not uncommon for ventricular tachyarrhythmias to be converted to "sporadic agonal activity" after they are broken with multiple shocks.

In response, the Trust asserts that the Estate has failed to establish a reasonable medical basis for its claim. To address the Supplemental Declaration of the Estate's attesting physician, the Trust submitted a Supplemental Declaration of the auditing cardiologist, Dr. Oliner[15], which stated, in relevant part, that:

> In accordance with the Trust's request, and in light of Claimant's Response, on October 11, 2007, I again reviewed Claimant's file, together with Claimant's Response, including the Supplemental Declaration of Dr. Manoj Muttreja ("Muttreja Supp. Dec."), which asserted for the first time that the multiple shocks administered by Emergency Medical Services ("EMS") personnel represent the Advanced Cardiac Life Support ("ACLS") protocol for ventricular tachycardia or ventricular fibrillation and not for bradyarrhythmias." Dr. Muttreja also asserts that it is "not uncommon for ventricular tachyarrhythmias to be converted to 'sporadic agonal activity' after they are broken with multiple shocks." (*See* Muttreja Supp. Dec.")
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> From this, Claimant seeks to draw the conclusion that there is a reasonable medical basis for the representation that she had ventricular fibrillation (VF) or sustained ventricular tachycardia (VT) which results in hemodynamic compromise.

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15. The Special Master permitted the Trust to submit the Supplemental Declaration of Dr. Oliner.

I do not disagree with the statement regarding ACLS protocol. However, in this case, the medical documentation - specifically the EMS notes - simply do not support a finding that the protocol was warranted. The first diagnosis of [decedent's] medical condition subsequent to the arrival of EMS personnel is recorded by EMS personnel as "sporadic agonal activity." (*See* EMS notes.) There is no observation - none whatsoever - of VF or VT. In addition, [decedent] was administered epinephrine and atropine. While epinephrine is indicated in situations where a patient experiences VF or VT (as well as for bradyarrhythmias or agonal activity), atropine is **only** indicated where a patient manifests bradyarrhythmias or agonal activity. [Emphasis in original.]

The EMS notes reflect only that "the monitor [on [decedent]] showed sporadic agonal activity." (*See* EMS notes.) There is no notation that [decedent] was at any time experiencing VT or VF.

The EMS notes for [decedent] are detailed and extensive. Given that, it is unlikely that if [decedent] was in fact experiencing VF or VT, it would have not been documented by the EMS personnel, or otherwise overlooked in their reporting.

This, coupled with the fact that atropine was administered to [decedent], is strong evidence that [decedent] did not have VT or VF but that she was experiencing agonal rhythms or bradyarrhythmias, as is documented in the EMS notes.

In light of the foregoing, I again affirm that it is my opinion that there is no reasonable medical basis for the GREEN Form representation that [decedent] had ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

In a sur-reply, the Estate asserted that the auditing cardiologist improperly interpreted the Settlement Agreement to require that the requisite ventricular tachycardia or ventricular fibrillation "be documented in order to qualify for benefits under the terms of the Settlement Agreement."

The Technical Advisor, Dr. Abramson, reviewed the entire Show Cause Record and concluded that there was a reasonable medical basis for the attesting physician's finding that the decedent suffered from ventricular fibrillation or sustained ventricular tachycardia, which resulted in hemodynamic compromise. In particular, Dr. Abramson determined that:

> Based upon my review of the Special Master's Record, including the Declarations of the Attesting Physician and the Auditing Cardiologist, the transthoracic echocardiogram from 8/28/99, the hospital records from 8/28/99-9/1/99, and the death certificate from 2/23/00, there is a reasonable medical basis for the Attesting Physician to state that [decedent] suffered from ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise.
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> The issue in this claim is what caused her sudden cardiac death-tachyarrythmia or bradyarrhythmia? The presence of the agonal rhythm on the monitor when the medics arrived is not helpful to differentiate between a tachyarrhythmia or bradyarrhythmia. The cardiac rhythm in most unwitnessed cases of sudden cardiac death is unknown; therefore the definition of sudden cardiac death does not rely upon the cardiac rhythm at the time of the event. In patients with dilated cardiomyopathies, ventricular tachycardia

> degenerating into ventricular fibrillation is the most common cause of sudden cardiac death and likely represents the events in this claimant.

After reviewing the entire Show Cause Record before us, we find that the Estate has established a reasonable medical basis for its claim. Under the Settlement Agreement, a claimant is entitled to Level V Matrix Benefits if the following conditions are met:

> (d) The individual otherwise qualifies for payment at Matrix Level II, III, or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

Settlement Agreement § IV.B.2.c.(5)(d).

The Estate's attesting physician, Dr. Muttreja, found that the decedent suffered from ventricular fibrillation or sustained ventricular tachycardia, which resulted in hemodynamic compromise. Although the Trust contested the attesting physician's conclusion, the Technical Advisor, Dr. Abramson, confirmed this finding.[16] Specifically, Dr. Abramson stated that "there is a reasonable medical basis for the Attesting Physician to conclude that this Claimant suffered from ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise."

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16. Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor Report.

The Technical Advisor's conclusion is also supported by the decedent's Death Certificate, which lists ventricular arrhythmias as an underlying cause of death. Moreover, the auditing cardiologist conceded that "most patients who die in this manner experience ventricular tachycardia or ventricular fibrillation." While the auditing cardiologist attempts to qualify his statements by asserting that such patients "typically do not then develop an agonal rhythm," given that the Settlement Agreement only requires a reasonable medical basis for the attesting physician's finding, we cannot affirm the Trust's denial based alone on the auditing cardiologist's equivocal statement.[17]

For the foregoing reasons, we conclude that the Estate has met its burden in proving that there is a reasonable medical basis for its claim, and is consequently entitled to Matrix A-1, Level V benefits. Therefore, we will reverse the Trust's denial of the claims submitted by the Estate and Richard Noble for Matrix Benefits.

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17. This is particularly true given that the Level V definition at issue does not require a claimant to rule out other causes to receive Level V benefits. Compare § IV.B.2.c.(5)(a) (Endocardial Fibrosis with a finding that "other causes . . . have been excluded"); § IV.B.2.c.(5)(d) (claimant need only have suffered from ventricular fibrillation or sustained ventricular tachycardia, which results in hemodynamic compromise).